

REMARKS

The Examiner has indicated that claims 31, 32, and 41-47, are allowed. (Paper No. 20060921 at 7). Previously, the Examiner also stated that claims 31-33 were allowed. (Office Action dated 3/29/2005, pp. 1 and 5). As noted above, it appears the Examiner has changed his mind, again, with respect to claim 33 in this Office Action. Again, "[p]iecemeal examination should be avoided as much as possible. ***The examiner ordinarily should reject each claim on all valid grounds available.***" MPEP § 707.07(g), 8th ed., Rev. 5, Aug. 2006, p. 700-128). This is the second time the Examiner has done this.

However, it is believed that the Examiner will finally conclude, in view of the arguments presented below, that the application is in condition for allowance.

Claim 31 has been amended to remove the phrase "for delivering a polysaccharide formulation to a respiratory tract of a mammal," and now simply recites "[a] system comprising"

Claim 40 has been amended to recite "1,2-dipalmitoyl-sn-glycero-3-phosphatidylcholine/1,2-dipalmitoyl-sn-glycero-3-phosphatidylglycerol (DPPC/DPPG)." It is submitted that one would readily understand the abbreviation but, for extra clarity, the full chemical name has been inserted.

No new matter has been introduced by the foregoing amendments. Approval and entry of the amendments is respectfully solicited.

Indefiniteness Rejection

Claims 38-40 were rejected under 35 USC § 112, second paragraph.
(Paper No. 20060921 at 2).

For the reasons set forth below, the rejection is traversed.

In making the rejection, the Examiner summarily contended that "[t]he phrase 'chemically modified', in claim 38, renders the claim indefinite. More specifically, it is unclear how said polysaccharide is chemically modified especially since there are numerous ways in which said polysaccharides can be modified, based on the functional groups they contain or possess." (*Id.*).

Initially, the Examiner's candid acknowledgement that "there are numerous ways in which said polysaccharide can be modified, based on the functional groups they contain or possess," demonstrates that the Examiner does in fact understand that the claims are broad, but not indefinite. The breadth of a claim does not make it indefinite. See MPEP § 2173.04; *Ex parte Balzarini*, 21 USPQ2d 1892, 1898 (BPAI 1991); and *Buell v. Beckstrom*, 22 USPQ2d 1128, 1133 (BPAI 1992).

In addition, the phrase "chemically modified" is defined in the specification at, for example, page 4, lines 23-26:

In one variation of the present invention, the polysaccharide may be chemically modified. Such modification may include cross-linking, addition of sulfate groups, addition of carboxyl groups, attachment of lipophilic side chains, introduction of acetyl groups, formation of an ester, and/or reaction with a carbodiimide.

Here, the Examiner has not made any factual determination that establishes that one of ordinary skill in the art would not have been able to ascertain with a reasonable degree of precision and particularity the particular area set out and circumscribed by the phrase "chemically modified." "Chemically modified" is a well known and understood phrase. It is broad, but not indefinite. And merely characterizing the phrase as "indefinite" does not satisfy the Examiner's burden and the fact that the phrase covers many possibilities, does not make it indefinite. For this additional reason, the rejection cannot stand and should be withdrawn.

The Examiner further asserted that "[t]he abbreviation or term 'DPPC/DPPG', in claim 40, renders the claim indefinite. More specifically, it is unclear what the abbreviation or term, DPPCDPPG designates or means." (Paper No. 20060921 at 2).

With a view towards furthering prosecution, claim 40 has been amended to recite "1,2-dipalmitoyl-sn-glycero-3-phosphatidylcholine/1,2-dipalmitoyl-sn-glycero-3-phosphatidylglycerol (DPPC/DPPG)." In view of the foregoing amendment, the rejection of claim 40 is rendered moot. Accordingly, withdrawal of the rejection is respectfully requested.

Enablement Rejection

Claims 33 and 39 were rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. (Paper No. 20060921 at 3).

In making the rejection, the Examiner asserted that "[a]pplicants are not enabled for the combinations of polysaccharide and a drug as claimed in claims 33 and

39.” (*Id.*). The Examiner further asserted that “the teachings of the book [Goodman & Gilman's: The Pharmacological Basis of Therapeutics, 10th Edition, McGraw-Hill Medical Publishing Division, 2001, pages 54-56] clearly support the fact that the instant claimed invention, which is drawn to a composition or system comprising a combination of any polysaccharide and any drug to be delivered to a respiratory tract of a host (e.g., a human) (as recited in claims 33 and 39), is highly unpredictable.” (*Id.* at 6).

To support the Examiner's argument, the Examiner asserted that “[a]s seen by Goodman & Gilman, the art of combination therapy is unpredictable. Drug-drug interactions are known to be beneficial or adverse, yet there is no way to know until the drugs are actually tested in combination with each other. Consequently, the utility of applicant's combination comprising a polysaccharide and any drug is highly unpredictable in light of the foregoing disclosure that pertains to the unpredictability of drug-drug interactions.” (*Id.*).

Initially, in response, it appears that the Examiner has misinterpreted the claims. The claims do not recite a method of treating anything. They do not require the administration of anything to anybody. And they do not require achieving any particular result. The claims are to systems that have compositions in containers.

Thus, whether there is any unpredictability in the way different drugs treat patients, is irrelevant - because the claims do not require treating anyone or achieving any particular result. All they require, is that one of skill in this art be able to combine certain elements together in a container as claimed. In any event, the statement of

Application No.: 09/863,849
Response Dated: February 1, 2007
Reply to Office Action of: August 2, 2006

intended use recited in the preamble has been removed to moot the Examiner's position completely.


In addition, a database search for the term "drug" in patent claims pulled up too many hits to even allow a review of the claims and the patents. Thus, it is believed that the USPTO has routinely allowed claims that recite "drug."

Moreover, as is well accepted, even a "considerable amount" of experimentation is permissible if it is merely routine or if the specification provides a reasonable amount of guidance. MPEP § 2164.05 and *In re Wands*, 8 USPQ at 1404. In addition, "a patent need not teach, and preferably omits, what is well known in the art." MPEP § 2164.01 (8th ed. Rev. 5, August 2006, p. 2100-187) citing *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

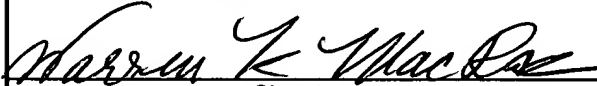
Thus, for the reasons set forth above, the enablement rejection should be withdrawn.

Application No.: 09/863,849
Response Dated: February 1, 2007
Reply to Office Action of: August 2, 2006

In view of the foregoing, favorable action on the merits, including entry of the amendments and withdrawal of each rejection and allowance of all claims, respectfully is submitted.

By: 

Warren K. MacRae
Reg. No. 37,876
BRYAN CAVE LLP
1290 Avenue of the Americas
New York, NY 10104
Tel. No.: (212) 541-2000
Fax No.: (212) 541-4630

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope with sufficient postage addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on February 1, 2007
Warren K. MacRae, Reg. No. 37,876
Name of applicant, assignee, or <u>Registered</u> Representative

Signature 02/02/2007
Date of Signature